



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,014	12/14/2001	Charles K. Brush	PU01112	2793

22840 7590 08/02/2006

GE HEALTHCARE BIO-SCIENCES CORP.
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,014	BRUSH ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 15-39 is/are pending in the application.
- 4a) Of the above claim(s) 15-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/2006 has been entered. Claims 1-3 and 11 have been amended. Claims 10, 12-14 have been canceled. Claims 1-9, 11, 15-39 are pending. Claims 15-39 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-9 and 11 are discussed in this office action.

Previous rejections

2. All previous rejections of the Final Office Action mailed on 10/31/2005 are withdrawn in view of Applicant's amendment and the new ground of rejections presented in this Office action.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS ARE NECESSITATED BY APPLICANT'S AMENDMENTS OF THE CLAIMS:

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 and 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-9 and 11 are indefinite in claim 1 at the recitation of "providing cRNA with at least one phosphorothioate moiety" because it cannot be determined how the "cRNA with the at least one phosphorothioate moiety" is provided. More specifically, it is unclear the nexus between the step of "providing cRNA with at least one phosphorothioate moiety" and the steps of performing *in vitro* transcription followed by microarray hybridization. It is suggested amending the claims such that it is clear that the incorporation of the phosphorothioate moiety with the cRNA occurs during the steps of *in vitro* transcription.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each

Art Unit: 1637

claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zoeller et al (The Journal of Histochemistry & Cytochemistry, vol. 45, no. 7, pages 1035-1041, 1997) in view of Yang et al (Genome Research, vol. 11, pages 1888-1898, November 7, 2001). Regarding claim 1, Zoeller et al teach a nucleic acid expression assay comprising in vitro transcription of target nucleic acid template to generate cRNA, wherein the method comprises providing said cRNA with at least one phosphorothioate moiety initiated by the labeling with an ³⁵S-UTP followed by *in situ* hybridization (Abstract and page 1036, col. 2, section entitled "cRNA probe and probe preparation).

The method of Zoeller et al differs from the instant invention in that the reference does not teach wherein said cRNA is contacted with a probe immobilized on a microarray to detect cRNA expression.

Yang et al et al teach methods of gene expression analysis using microarrays (BeadArrays). Yang et al provides an embodiment wherein in vitro transcription of target nucleic acid template is performed to generate cRNA and wherein said cRNA is contacted with a probe immobilized on a microarray under conditions to allow hybridization between said cRNA and said probe and detecting hybridized cRNA to assay expression of said target nucleic acid template (see Figure 5 and legend & page 1896, section entitled "Total RNA extraction and cRNA labeling"). Yang et al teach that microarray analysis via the use of a geneChip or BeadArray is a reliable method

for monitoring expression levels of several thousand genes simultaneously (page 1894, col. 2, lines 23-25). Yang et al further teach that the BeadsArray analysis method offers affordable cost, rapid speed, and high flexibility with capability for high throughput assay that are increasingly needed. Yang teaches that it is ideal for applications such as diagnostic detecting of disease genes from clinical samples and screening of characteristic marker genes from many biological systems (col. 1895, col. 2, first paragraph under section entitled "Discussion"). Therefore, one of ordinary skill in the art at the time of the claimed invention would have been motivated to incorporate a step of detecting cRNA expression via microarray (BeadsArray) analysis for the numerous benefits taught by Yang et al that incorporating microarray analysis as a means of detecting expression is advantageous because it offers an affordable cost, rapid speed, and high flexibility with capability for high throughput analysis.

Conclusion

8. No claims are allowed. However, the claims 2-9 and 11 have not been rejected under prior art because the art does not provide a suggestion or motivation for further labeling or the attachment of a reporter group since the radiolabel ^{35}S is present.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax

Art Unit: 1637

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.

Patent Examiner

Art Unit 1637

7/27/2006